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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/030,805	05/10/2002	Bernd Klemm	SMB-PT038(PC 00 430 B US)	5612
3624	7590	09/09/2004	EXAMINER	
VOLPE AND KOENIG, P.C. UNITED PLAZA, SUITE 1600 30 SOUTH 17TH STREET PHILADELPHIA, PA 19103			FORD, ALLISON M	
			ART UNIT	PAPER NUMBER
			1651	

DATE MAILED: 09/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

MS

Office Action Summary

Application No.

10/030,805

Applicant(s)

KLEMM ET AL.

Examiner

Allison M Ford

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-23 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10 May 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☒ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

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DETAILED ACTION

Status of Application

Claims 1-23 are pending in the current application.

Priority

Receipt is acknowledged of papers submitted under 35 U.S.C. 371, which papers have been placed of record in the file. Additionally, acknowledgment is made of applicant's claim for foreign priority based on a PCT filed on 07/07/2000, which further claims priority to a German application filed on 07/13/1999. It is noted, however, that applicant has not filed a certified copy of the German national patent application, Serial No. 199 32 375.5, as required by 35 U.S.C. 119(b).

Specification

Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

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The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

The abstract of the disclosure is objected to because it contains multiple paragraphs. The abstract should consist of a single paragraph of under 150 words. Correction is required. See MPEP § 608.01(b).

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-17 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for preservation of animal and human material, does not reasonably provide enablement for preservation of microorganisms or similar material. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The claimed method is intended for preservation of organs or whole bodies for transplants and/or medical research/training. The improvement of the current invention over previous preservation methods is the ability to maintain organs and bodies at peak freshness by first preserving the materials and then supplying the material with a through-flushing by fluid, to stimulate blood circulation. Through-flushing is clearly not feasible with microorganism, as they

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have no circulatory system, thus the system is not enabled to adequately preserve microorganisms or similar material.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is directed to a method of preserving animal and human preparations. Claim 17 is directed to a device for preserving animal and human preparations. It is unclear what is meant by the term “preparations,” as it is not explicitly defined in the claims, or in the specification. It is unclear if the applicant is referring to the ‘material to be treated,’ if so a single term of reference should be used; or if the term “preparations” has special limitations, such as it refers to only parts of animals or humans, parts that are intended for further use, or preparation of specific cells or tissues, etc, the limitations need to be clearly defined. Further, it is unclear if the preparations refer to the microorganisms or similar material to be treated, or if the term is specific to only animal and humans. Additionally, claims 8 and 10 include reference to “part preparations,” as “preparations” is not defined, “part preparations” are indefinite for the same reasons. Claims 2-16 are subject to the limitations of claim 1 and thus are indefinite. Claims 18-23 are subject to the limitations of claim 17 and thus are indefinite.

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Claim 1 is further rejected as being confusing and therefore indefinite because it contains such long recitations and unimportant details that the scope of the claimed invention is clouded, and thus the metes and bounds of the claimed subject matter cannot be determined. The preamble discloses the method to be usable on animal and human preparations as well as microorganisms or similar material for the purpose of medical research and/or training as well as for the purpose of prolonging the viability of organs and body parts intended for transplantation. It is unclear if the preambles are meant to be limitations, it would be more appropriate to include these in the disclosure as intended uses, and thereby not impose limitations.

Claim 5 is further rejected as being confusing and therefore indefinite. Claim 5 requires the periodic pressuring *for a portion* of the material to be treated to be carried out over a specified time span. It is unclear what applicant means by 'a portion' of the material to be treated. If the material is separated and treated by pressurization in separate treatments this must be clearly stated. If the different portions of the same material are subjected to different pressurizations in the same treatment, this must be clearly stated and explained.

Claim 6 is further rejected as being confusing and therefore indefinite. Claim 6 requires the time span for the periodic pressuring to be chosen based on the allocating maximum pressure and/or the material to be treated. It is unclear what the applicant means by "allocated maximum pressure," it is unclear if it is referring to the maximum pressure of the vessel, or of the material to be treated. It must be stated what the "allocated maximum pressure" is referring to.

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Claims 8, 11, and 12 are further rejected as being confusing and therefore indefinite.

Claim 8 requires the blood vessel system of a preparation, formed by a part preparation or a complete body or an organ or body part, is flushed through before and/or during and/or after preservation with a particularly anti-clotting fluid or a blood substitute or the like. It is unclear how a part preparation or a complete body or an organ or body part forms the blood vessel system of the preparation. A complete body or an organ or a body part may have an existing blood vessel system, which can be flushed-through with an anti-clotting fluid or a blood substitute or the like; but they cannot cause the formation of a blood vessel system. Further, it is not clear what is intended by the phrase "a particularly anti-clotting fluid;" if applicant intended to require a *particular* anti-clotting fluid, the type of anti-clotting fluid must be specified. As written the claim is unclear and confusing, and therefore indefinite. Claims 11 and 12 are dependent on claim 8, and thus have the same limitations, therefore claims 11 and 12 are also indefinite.

Claims 9 and 10 are further rejected as being unclear and therefore indefinite. Claims 9 and 10 require the organ or body part to be connected before and/or during and/or after the preservation to a through-flushing by fluid, preferably to an artificial blood circulation. It is unclear how the organ or body part is structurally connected to the fluid. A fluid cannot be connected to an object; rather it can be delivered via a structure such as a valve or hose. Additionally this claim contains a broad limitation followed by a narrow limitation. A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly

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set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claims 9 and 10 recite the broad recitation "a through-flushing fluid", and the claim also recites "an artificial blood circulation," which is the narrower statement of the range/limitation.

Furthermore, claim 10 recites the limitation "the material to be treated with at least one large blood vessel" in line 6 of the claim. None of the previous claims specified that the organ or body part comprise at least one large blood vessel; therefore there is insufficient antecedent basis for this limitation in the claims.

Claim 10 is still further rejected as being unclear and indefinite. Claim 10 requires the large blood vessel (ln 6 of the claim) to be connected to a pulsating fluid supply. It is unclear of the structural connection between the large blood vessel and the "preferably pulsating fluid supply." Even still further, it is unclear what is meant by a "preferably pulsating fluid supply," the fluid supply must be contained in a container or vessel, as fluid is not self containing, this container or vessel is not described. Again, the structural relationship between the fluid supply container and the one large artery and/or at least one vein (ln 7 of the claim) is not adequately

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described. Additionally, it is not clear how the fluid supply pulsates, if there is a pump or an energy source which causes the pulsation, this must be adequately described and claimed.

Therefore claim 10 is unclear and confusing, and thus indefinite.

Claim 11 recites the limitation "blood circulations of the preparation *or the like* " in line 2 of the claim. There is insufficient antecedent basis for this limitation in the claim. Claim 8 recites a blood vessel system, if applicant intends to refer to the same component, the same terminology must be used; furthermore, claim 8 makes reference to the blood vessel system of only the preparation, not alternatives, which would be encompassed by "or the like."

Claim 12 recites the limitation "blood substitute or similar fluids" in line 2 of the claim. There is insufficient antecedent basis for this limitation in the claim. Claim 11 only makes reference to blood substitute, not similar fluids. Claim 12 also recites the limitation "blood stream" in line 2 of the claim. There is insufficient antecedent basis for this limitation in the claim. It appears applicant is intending to refer to the blood vessel system of claim 8, if so the same terminology must be used.

Claim 12 is further rejected as being unclear and therefore indefinite. Claim 12 requires a pressure pump to be connected to at least one blood vessel. It is unclear of the structural connection between the pump and the blood vessel, if the blood vessel is a blood vessel of the preparation's blood vessel system, or a separate vessel connecting the pump to the preparation. Therefore claim 12 is unclear and indefinite.

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Claim 14 is further rejected as being unclear and therefore indefinite. Claim 14 requires the atmospheric pressure to be compressed, stored intermediately at a pressure between 10 bar and 1000 bar, and then supplied to the vessel. Atmospheric pressure is a force equal to 1 atm, it cannot be compressed; atmospheric air can be compressed. Further, it is not clear where the air is stored and compressed prior to being supplied to the vessel, as air needs to be contained. The supplementary container is not clearly defined, and therefore the claim is indefinite.

Claim 16 is further rejected as being unclear and therefore indefinite. Claim 16 requires the vessel to be cooled, and that the time spans of the periodic pressure increase and decrease are determined so that at the end of each time span a specifiable temperature will prevail in the vessel. It is unclear if applicant is intending to claim the length of the time span of the pressure change will determine the end temperature in the vessel, if so it needs to be stated explicitly. Further, the specifiable temperature must be specified. Therefore the claim is unclear and thus indefinite.

Claims 21 and 23 are further rejected as containing a broad limitation followed by a narrower limitation. A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by

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raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 21 recites the broad recitation "in a cooled ambient environment"; and the claim also recites "in a cooling chamber" which is the narrower statement of the range/limitation.

Claim 22 is further rejected as being unclear and therefore indefinite. It is unclear if the "cooling jacket" is the same as the "cooling chamber" recited in claim 21. If they are related, the relationship or structural modification between them must be explained; if they are not the same they must be defined as to their differences.

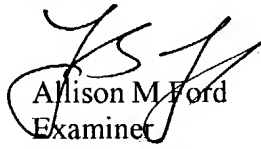
Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Allison M Ford whose telephone number is 571-272-2936. The examiner can normally be reached on M-F 7:30-4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0927. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Allison M. Ford
Examiner
Art Unit 1651

AMF